K082363

APR 2 9 2009

510(k) SUMMARY

Date: 15th December 2008

Submitted By: Ms Milica Talic
QA/RA Manager
Cook Australia
12 Electronics Street
Brisbane Technology Park
Eight Mile Plains
Queensland, Australia. 4113

Device:

Trade Name: **COOK Sydney IVF Blastocyst Vitrification Kit**
COOK Sydney IVF Blastocyst Warming Kit

Common name: Blastocyst Vitrification & Warming Kits

Proposed Classification Name: Reproductive media & supplements
21 CFR Part 884.6180 (87MQL)
Class II

Predicate Devices:

Cook Sydney IVF Blastocyst Vitrification & Warming Kits are comparable to predicate devices described by criteria set forth in the final rule [63 FR 48428]. The predicate device used as the basis for this application is Vit Kit Freeze/Vit Kit Thaw (K060168) manufactured by Irvine Scientific Sales, Santa Ana, California.

Device Description:

Cook Sydney IVF Blastocyst Vitrification and Warming Kits are intended for the vitrification, containment and re-warming of human blastocysts as part of human ART procedures. Vitrification involves the rapid freezing of the embryo and is defined as the solidification of a solution at a temperature below its glass transition temperature by extreme elevation in viscosity using high cooling rates (15 000 to 30 000 °C/min) rather than crystallisation. The Cook Sydney IVF Vitrification and Warming Kits are comprised of HEPES buffered solutions containing physiological salts and the cryoprotectants ethylene glycol, DMSO and trehalose.

Intend use:

'Cook Sydney IVF Blastocyst Vitrification Kit' is intended for the vitrification of Human blastocysts for ART procedures. This kit is designed for use with Cook Sydney IVF Blastocyst Vitrification Warming Kit

'Cook Sydney IVF Blastocyst Warming Kit' is intended for the recovery of Human blastocysts that have undergone vitrification using Cook Sydney IVF Blastocyst Vitrification Kit for ART procedures.

The only difference in the intended use of the Cook product and that of the predicate device relates to some wording. Irvine (the predicate's manufacturer) uses the phrase "ultra-rapid freezing" instead of vitrification, however, the meaning is the same.

Comparison to the predicate device:

Device / Element	Cook Sydney IVF Vitrification	PREDICATE Irvine Scientific Vitrification (K060168)
Intended Use	**Cook Sydney IVF Blastocyst Vitrification Kit** is intended for the vitrification and containment of Human blastocysts for ART procedures. This kit is designed for use with Cook Sydney IVF Blastocyst Vitrification Warming Kit **Cook Sydney IVF Blastocyst Warming Kit** is intended for the recovery of Human blastocysts that have undergone vitrification and containment using Cook Sydney IVF Blastocyst Vitrification Kit for ART procedures.	**Vit Kit - Freeze** is intended for ultra-rapid freezing and containment of human blastocysts for Assisted Reproductive Technology (A.R.T.) procedures. This kit is designed for use with Irvine Scientific's Blastocyst Vitrification Thaw Kit (Vit Kit – Thaw) for optimal recovery of specimens. **Vit Kit - Thaw** is intended for the recovery of human blastocysts that have undergone ultra-rapid freezing and containment using Irvine Scientific's Blastocyst Vitrification Freeze Kit (Vit Kit - Freeze) for Assisted Reproductive Technology (ART) procedures.
Principal of Operation	Provides users with the ability to cryopreserve supernumerary embryos created during the in vitro fertilization procedure and then to re-warm them for use at a future point in time.	Provides users with the ability to cryopreserve supernumerary embryos created during the in vitro fertilization procedure and then to re-warm them for use at a future point in time.
Formulation	HEPES buffered physiologic media containing ethylene glycol, DMSO, trehalose, HSA & gentamicin in addition to the normal physiological salts.	Media 199 based physiologic media containing, ethylene glycol, DMSO and sucrose in addition to the normal physiological salts
Package	Borosilicate Class I vials packaged into a cardboard outer box	Borosilicate Class I vials

Clinical Efficacy:

The vitrification media and warming kits have been used in clinical practice at Sydney IVF, Sydney, Australia. The results in clinical practice support the safety and efficacy of the product, returning a suitable pregnancy rate.

Bench Testing:

Satisfactory safety of the product has been determined through the following tests:

- pH testing
- osmolality
- two-cell mouse embryo assay (MEA)
- bacterial endotoxin (LAL)

The vitrification and warming media passed all the requirements of these tests.

COOK Australia verify the following items have been met:

- This summary includes only information that is provided in the body of this 510(k).

- This summary does not contain any puffery or unsubstantiated labelling claims.
- This summary does not contain any raw data, it contains only summary data.
- This summary does not contain any trade secret or confidential commercial information.
- This summary does not contain any patient identification information.

The device is similar with respect to intended use & technological characteristics to the FDA published predicate device description.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Gus Taddeo
Managing Director
William A. Cook Australia PTY, Ltd.
12 Electronics Street
Eight Mile Plains
Queensland 4113
AUSTRALIA

APR 2 9 2009

Re: K082363
Trade/Device Name: Cook Sydney IVF Blastocyst Vitrification Kit
Cook Sydney IVF Blastocyst Warming Kit
Regulation Number: 21 CFR §884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product code: MQL
Dated: March 26, 2009
Received: April 17, 2009

Dear Mr. Taddeo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K082363

Device Name: **Cook Sydney IVF Blastocyst Warming Kit**

Indications for Use:

Blastocyst Warming Kit is intended for the recovery of human blastocysts that have undergone vitrification using COOK Sydney IVF Blastocyst Vitrification Kit (K-SIBV-5000) for ART procedures.

Prescription Use __Y_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K082363

INDICATIONS FOR USE

510(k) Number (if known): K082363

Device Name: **Cook Sydney IVF Blastocyst Vitrification Kit**

Indications for Use:

Blastocyst Vitrification Kit is intended for the vitrification of human blastocysts for assisted reproduction procedures (ART). This kit is designed for use with Blastocyst Warming Kit (K-SIBW-5000)

Prescription Use __Y_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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